

a human. Examples of allergic disorder include, but are not limited to, allergic rhinitis, solar urticaria, or symptomatic dermographism.

5 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 depicts the chemical structure of norastemizole.

10 Figure 2 presents in bar-graph format the change in initial potency of a dosage form of norastemizole and various pharmaceutical excipients when the dosage form is exposed to a temperature of 60°C at 75% relative humidity using non-hermetically sealed containers (i.e., screw-top vials).

DETAILED DESCRIPTION OF THE INVENTION

Applicants have discovered that, even in the
15 absence of applied heat, surprisingly, the discoloration reaction found with primary amines and lactose is also found with norastemizole. Thus, there appears to be an heretofore unappreciated incompatibility between the secondary amine, norastemizole, and lactose. It is, therefore, desirable to
20 formulate dosage forms of norastemizole that are lactose-free. Further, Applicants have also discovered that the instability of lactose and norastemizole may be initiated and/or accelerated upon the exposure of a norastemizole/lactose formulation to water, including
25 atmospheric moisture, e.g., humidity. The instability is also initiated and/or accelerated upon exposure to heat at temperatures of greater than about 60°C. Moreover,
Applicants have also discovered that the instability of lactose and norastemizole may be initiated and/or accelerated by the high surface area of the small particles of
30 norastemizole conventionally used in pharmaceutical compositions upon the exposure of a norastemizole/lactose formulation. Additionally, Applicants have also discovered